

REMARKS/ARGUMENTS

Claim Objection

Claims 1-17 were objected to as lacking the term "adenosine" before the term "5'-monophosphate-activated protein kinase". The applicant agrees and amended the claim accordingly.

35 USC § 112, first paragraph

Claims 1-17 were rejected under 35 USC § 112, first paragraph, as failing to comply with the written description requirement. More specifically, the office noted that the compound was described only by its function. The applicant agrees in some respect and disagrees in others. Nevertheless, the applicant amended the claims to now include specific method steps and remove functional language as identified by the examiner.

35 USC § 112, second paragraph

Claims 1-17 were rejected under 35 USC § 112, first paragraph, as being indefinite. In light of the amendments made to the claims and further comments above, the rejection should be moot. With respect to the term "thaumatin-like protein" it is noted that such term is a term of art specific to a protein (see *e.g.*, Hejgaard et al. (FEBS) as applied by the office, or Allergy. 2004 May;59(5):479-81) and the person of ordinary skill in the art is therefore well apprised of the scope of that term.

Double Patenting

Claim 17 was provisionally rejected under the judicially created doctrine of double patenting over claims 1-26 and 1, 58, 15-17 of co-pending applications 10/469384 and 10/220761, respectively. Claim 17 was amended and should no longer be within double-patenting scope of the above cited claims. Should the office maintain the obviousness double patenting rejection despite the amendments, the applicant will file terminal disclaimers as appropriate.

35 USC § 102(b)

Claims 16-17 were rejected under 35 USC § 102(b) as being anticipated by Hejgaard et al (FEBS). The applicant respectfully disagrees for various reasons. Among other things, amended claim 16 requires a step of "...removing a thaumatin-like protein..." In contrast, Hejgaard collects the thaumatin-like protein as the desired fraction while the method of claim 16 discards the thaumatin-like protein.

Moreover, and as properly acknowledged by the office, Hejgaard fails to teach use of malted barley grains. Such difference is far from being trivial as malting significantly affects the physiological and anatomical properties of a seed: Malting is a process applied to cereal grains, in which the grains are made to germinate to form grain rootlet at one end and tunnels beneath the grain husk to the other end of the grain. Malting/germination results in a switch in metabolic stance effecting *inter alia* energy liberation of previously accumulated energy reserves, reversion of growth inhibition to growth initiation, photoresponse, etc. Therefore, contents of an extract of malted seeds will present a significantly changed compositional profile (largely flour of seeds as compared to complex and more plant-like material at/after germination), and the office's assertion that the malted seed would ***inherently*** comprise the compound is unsupported. "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly ***inherent characteristic necessarily flows*** from the teachings of the applied prior art." Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). In view of the above, the applicant believes that this high standard of proof was not met by the office.

Claims 1-5, 8-12, and 15-17 were rejected under 35 USC § 102(b) as being anticipated by Hsia et al (U.S. Pat. No. 6,270,774). The applicant respectfully disagrees for various reasons.

With respect to claims 1-5 and 8-9, it is noted that Hsia entirely fails to address AMPK, let alone a method of AMPK activation. Furthermore, the specific methods steps of claim 1 are also not found in Hsia. It is well established that anticipation under 35 U.S.C. § 102 requires the presence in a single prior art disclosure of ***each and every element of a claimed invention***.

Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d 628, 631, 2 U.S.P.Q.2D (BNA) 1051, 1053 (Fed. Cir. 1987); *Carella v. Starlight Archery*, 804 F.2d 135, 138, 231 U.S.P.Q. (BNA) 644, 646

(Fed. Cir.), *modified on reh'd*, 1 U.S.P.Q.2D (BNA) 1209 (Fed. Cir. 1986); [**7] *Jamesbury Corp. v. Litton Indus. Prods., Inc.*, 756 F.2d 1556, 1560, 225 U.S.P.Q. (BNA) 253, 256 (Fed. Cir. 1985); *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1458, 221 U.S.P.Q. (BNA) 481, 485 (Fed. Cir. 1984); *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548, 220 U.S.P.Q. (BNA) 193, 198 (Fed. Cir. 1983).

Still further, the office alleges that as the composition taught by Hsia "...contains a barley extract, it also, therefore, contains a compound which has the structure of a compound purified from an extract of barley malt as instantly claimed. Such assertion was not reasonably supported and is not well taken by the applicant (see comments below). A germinating seed is simply not a barley grass extract as proposed by the office. Should the examiner maintain such position, proper reasoning should be provided.

With respect to **claims 10-12 and 15**, it is noted that these claims expressly require the activation of AMPK as claimed in claim 1 and therefore the same arguments as provided above apply.

With respect to **claims 16-17**, it is noted that these claims are directed to a process of purifying a compound from an extract of ground barley malt, which is neither taught nor suggested by Hsia et al. All Hsia teaches is preparation of a barley grass extract, which is entirely inconsistent with extraction of a germinating (malted) barley seed.

35 USC § 103

Claims 1-15 were rejected under 35 USC § 103 as being obvious over Hsia in view of Kannel (Am. Heart Journal). It is entirely unclear to the applicant how Hsia and Kannel could be properly combined to render claims 1-15 obvious.

It should be pointed out that to establish prima facie obviousness of a claimed invention, *all the claim limitations must be taught or suggested by the prior art*. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

First, claim 1 is directed to a method of activating adenosine 5'-monophosphate-activated protein kinase, which is neither taught nor suggested in either reference. Second, claim 1 expressly recites several method steps of preparing a low-molecular weight composition, none of which are found in the cited art. Hsia merely points to commercially available forms of barley grass extracts.

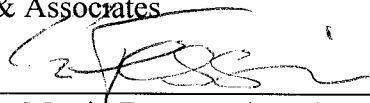
With respect to Kannel it is pointed out that this reference simply teaches the significance of HDL/LDL ratios in connection with risk factors for incidence of cardiovascular disease. Thus, Kannel fails to remedy the defects of Hsia. Moreover, there is simply nothing in the Kannel reference that would lead to a combination with Hsia such as to arrive at the presently claimed subject matter.

In view of the present amendments and arguments, the applicant believes that all claims are now in condition for allowance. Therefore, the applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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